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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,813	01/24/2002	John C. Reed	P-LJ 5144	4255

23601 7590 09/09/2004

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,813	REED ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending in the application and are currently under prosecution.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Claim 24 is a linking claim, linking groups 1-3. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 24 . Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1, claims 1-7, 12, drawn to the nucleic acid molecules, a vector, a recombinant cell, and a method for expressing an SBP1 polypeptide, classified in class 536, subclass 23.1

Group 2, claims 8-11, 34, drawn to the SBP1 polypeptide of SEQ ID NO:14, a fragment thereof, or a chimeric protein, classified in class 530, subclass 350.

Group 3, Claims 13-16, drawn to an antibody to SEQ ID NO:14, classified in class 530, subclass 387.1.

Group 4, Claim 17, drawn to a transgenic non-human mammal expressing SEQ ID NO:13, classified in class 800, subclass 2.

Group 5, Claims 18-19, drawn to a method for detecting a SBP polynucleotide, classified in class 435, subclass 6.

Group 6, Claim 20, drawn to a method for detecting a SBP polypeptide, classified in class 435, subclass 7.1.

Group 7, Claim 21, drawn to a method for identifying an agent that alters the association of SBP1 with a SBP1 associated polypeptide, classified in class 435, subclass 7.1.

Claims 22-23 are linking claims, linking groups 8-9. Claim 25 is a linking claim, linking groups 8, 10-11. Claim 28 is a linking claim, linking groups 8-11. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claims 22, 23, 25, 28. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 8, drawn to a method for modulating apoptosis or treating cancer, using the nucleic acid molecule that expresses SBP1 polypeptide, or an antisense, or a polynucleotide compound that alters the association of SBP1 with a SAP in a cell, or alters the activity of SBP1 in a cell, classified in class 514, subclass 44.

Group 9, drawn to a method for modulating cell division, using the nucleic acid molecule that expresses SBP1 polypeptide, or an antisense, or a polynucleotide compound that alters the association of SBP1 with a SAP in a cell, or alters the activity of SBP1 in a cell, classified in class 514, subclass 44.

Group 10, drawn to a method for modulating apoptosis or treating cancer, using the SBP1 polypeptide, or a non-antibody polypeptide compound that alters the association of SBP1 with a SAP in a cell, or alters the activity of SBP1 in a cell, classified in class 514, subclass 2.

Group 11, drawn to a method for modulating apoptosis or treating cancer, using an antibody specific for SBP1 polypeptide, or an antibody compound that alters the association of SBP1 with a SAP in a cell, or alters the activity of SBP1 in a cell, classified in class 424, subclass 130.1.

Claim 26 is a linking claim, linking groups 12-14. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 26. Upon the allowance of the linking claim(s), the restriction

requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 12, Claim 27, drawn to a method for diagnosing a pathology characterized by an increased or decreased level of SBP1, using an anti-SBP1 antibody, classified in class 435, subclass 7.1.

Group 13, Claim 27, drawn to a method for diagnosing a pathology characterized by an increased or decreased level of SBP1, using an SBP1 associated polypeptide, which is not an antibody, classified in class 435, subclass 7.1.

Group 14, Claim 27, drawn to a method for diagnosing a pathology characterized by an increased or decreased level of SBP1, using a SBP1 nucleic acid molecule, classified in class 435, subclass 6.

Claim 29 is a linking claim, linking groups 15-19. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction

requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 15, Claim 30, drawn to a method for identifying a site on Survivin that interacts with SBP1, using mass spectrometry, classified in class 435, subclass 7.1.

Group 16, Claim 30, drawn to a method for identifying a site on Survivin that interacts with SBP1, using photoaffinity labeling, classified in class 435, subclass 7.1.

Group 17, Claim 30, drawn to a method for identifying a site on Survivin that interacts with SBP1, using NMR, classified in class 435, subclass 7.1.

Group 18, Claim 30, drawn to a method for identifying a site on Survivin that interacts with SBP1, using X-ray crystallography, classified in class 435, subclass 7.1.

Group 19, Claims 30-31, drawn to a method for identifying a site on Survivin that interacts with SBP1, using virtual computational methodology, classified in class 435, subclass 7.1.

Claim 32 is a linking claim, linking groups 20-23. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 32. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 20, claim 33, drawn to a method for identifying a compound that binds to SBP1 polypeptide, using mass spectrometry, classified in class 435, subclass 7.1.

Group 21, claim 33, drawn to a method for identifying a compound that binds to SBP1 polypeptide, using NMR, classified in class 435, subclass 7.1.

Group 22, claim 33, drawn to a method for identifying a compound that binds to SBP1 polypeptide, using virtual computational methodology, classified in class 435, subclass 7.1.

Group 23, drawn to a method for identifying a compound that binds to SBP1 polynucleotide, classified in class 435, subclass 6.

Group 10 is further subject to election of a single disclosed species.

Claims 25, 28 are generic to a plurality of disclosed patentably distinct species comprising:

1) the SBP1 polypeptide, or

2) a non-antibody polypeptide compound that alters the association of SBP1 with a SAP in a cell, or alters the activity of SBP1 in a cell.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Inventions 5-23 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups (1) and (5, 8, 9, 14, 23) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid molecule can be used for making recombinant proteins, as opposed to its use in treating cancer.

The inventions of Groups (2) and (7, 10, 15-22) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be

practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide can be used for making antibodies, as opposed to its use treating cancer.

The inventions of Groups (3) and (6, 11, 12) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography, as opposed to its use in treating cancer.

The inventions of Groups (1) and (6, 7, 10-13, 15-22) are not at all related because the nucleic acid of Group I is not used in any of the methods of Groups 6, 7, 10-12, 15-22.

The inventions of Groups (2) and (5, 6, 8-9, 11-14, 23) are not at all related because the polypeptide of Group 2 is not used in any of the methods of Groups 5, 6, 8-9, 11-12, 14, 23.

The inventions of Groups (3) and (5, 7, 8-10, 13-23) are not at all related because the antibody of Group 3 is not used in any of the methods of Groups 5, 7, 8-10, 14-23.

The inventions of Groups (4) and (5-23) are not at all related because the transgenic mammal of Group 4 is not used in any of the methods of Groups 5-23.

The species are distinct, because they structurally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and because the searches for different groups are not co-extensive, and it would be an undue experimentation of the Examiner to search all the groups together, restriction for examination purposes as indicated is proper (see MPEP 806.04(a)-806.04(i), 808.01(a), 808.02, 806.05-806.05(i)).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement could be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

September 01, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER